

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### The effect of Occupational Therapy Intervention Process Model (OTIPM) on occupational performance and satisfaction of patients with chronic stroke and comparing it with conventional occupational therapy

#### Protocol summary

##### Study aim

to investigate the effect of occupational therapy based on the OTIPM model on occupational performance and the level of satisfaction of chronic stroke patients in comparison with traditional occupational therapy.

##### Design

A concealed clinical trial with control group, parallel groups, single blind, and block randomization by using random numbers table. Sample are recruited from stroke rehabilitation clinics in Tehran and sample size will be determined after a pilot study.

##### Settings and conduct

Setting for control and intervention groups are outpatient clinic and home respectively. Patients participate in one hour for each session, three times per week during ten weeks interventions. Assessor will be blind in this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: stroke patients with age range of 18 to 65 years, Brunnstrom score over 3, MMSE  $\geq$  21, living at home, at least 6 months post stroke with occupational therapy referral. People with acute heart diseases, serious psychological problems or other neurological diseases, are excluded from the study.

##### Intervention groups

The traditional occupational therapy interventions: neurodevelopmental treatment, Bobath technique, proprioceptive neuromuscular facilitation, pain management, gross and fine manual dexterity training are provided to the participants. The occupational therapy intervention based on the OTIPM model includes: 1- Prioritization of Activity Daily Living (ADL) by client 2- Observation and analysis of client while performing challenging ADL by the occupational therapist 3-Defining contributing factors for ineffective occupational performance 4- Defining treatment goals 5- Implementation of interventions (compensatory, educational, acquisition and restoration).

#### Main outcome variables

Occupational performance and satisfaction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160808029260N5**

Registration date: **2023-05-13, 1402/02/23**

Registration timing: **prospective**

Last update: **2023-05-13, 1402/02/23**

Update count: **0**

##### Registration date

2023-05-13, 1402/02/23

##### Registrant information

##### Name

Afsson Hassani Mehraban

##### Name of organization / entity

Iran University of Medical Sciences

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Iran (Islamic Republic of)

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-23, 1402/07/01

##### Expected recruitment end date

2024-05-19, 1403/02/30

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of Occupational Therapy Intervention Process Model (OTIPM) on occupational performance and satisfaction of patients with chronic stroke and comparing it with conventional occupational therapy

**Public title**

Investigating the impact of occupational therapy based on daily life activities on the performance and satisfaction level of stroke patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Occurrence of a stroke Age 18 to 65 years Branstrom above 3 MMSE above 21 Living at home At least 6 months have passed since the stroke The doctor has referred the person to receive occupational therapy services

**Exclusion criteria:**

People have acute heart diseases (such as acute heart attack) People have serious psychological diseases (such as depression and psychiatric disorders) People have neurological diseases (such as recurrent stroke, Parkinson's, dementia, seizures)

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using a table of random numbers by a person who has no contact with the patients, the patients are placed in two groups in the form of random blocks, the patients in the first group received conventional occupational therapy treatments and in the second group received occupational therapy based on the OTIPM model (the main intervention).

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The present study is single blind (evaluator).

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Iran University of Medical Sciences

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Iran University of Medical Sciences, Next to Milad tower, Hemmat Highway

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1449614535

**Approval date**

2023-05-01, 1402/02/11

**Ethics committee reference number**

IR.IUMS.REC.1402.078

**Health conditions studied****1****Description of health condition studied**

Stroke

**ICD-10 code**

I67

**ICD-10 code description**

Other cerebrovascular diseases

**Primary outcomes****1****Description**

Occupational performance (a dynamic interaction involving the person, context/environment, and activity or occupation) is the focus of occupational therapy practice. including skills (purposeful actions to perform occupations such as motor skills, processing skills, social interaction skills), patterns (temporal elements of occupation such as routines, habits, roles, rituals) and domains (work/productivity, play/leisure (such as play), sports, hobbies) are the basic and functional activities of daily living such as rest/sleep)

**Timepoint**

Before the intervention, after 10 weeks of intervention, the first and third month after the end of the intervention

**Method of measurement**

Occupational performance is measured with the help of COPM and ADL taxonomy scores

**2****Description**

Satisfaction: the degree of satisfaction of people with occupational performance and the match between occupational participation and performance expectations

#### **Timepoint**

Before the intervention, after 10 weeks of intervention, the first and third month after the end of the intervention

#### **Method of measurement**

The score of the COPM questionnaire

## **Secondary outcomes**

### **1**

#### **Description**

Functional performance: Physiological functions of body systems

#### **Timepoint**

Before the intervention, after 10 weeks of intervention, the first and third month after the end of the intervention

#### **Method of measurement**

In this study, body functions are measured with the help of ARAT, FMA and SIS questionnaire scores.

## **Intervention groups**

### **1**

#### **Description**

Intervention group: The intervention of the second occupational therapy group is based on the OTIPM model (main intervention). In this group, once the client has prioritized which activities of daily living should be addressed, the occupational therapist, after observing the challenging activities of daily living of the person in the natural context of the client, analyzes the ineffective skills and tasks in performing the performance of each prioritized task (occupation). And it takes into account person effective factors, including body function, task needs, or the influence of the environment in the implementation of occupation. After completing the performance analysis, the occupational therapist and the clients work together to create client-centered and occupation-centered goals, and there are four choices in the intervention stage: compensatory, educational, acquisition, and restoration (steps of implementing this intervention in the attached file) The full length has been described (23, 33). This group of interventions with the presence of an occupational therapist at home and three sessions a week, for ten weeks and each session is one hour, These interventions are implemented by the researcher who has trained the model implementation courses.

#### **Category**

Rehabilitation

### **2**

#### **Description**

Control group: The intervention of the first group includes conventional occupational therapy interventions. These interventions included neurodevelopmental treatment, Bobath technique,

facilitation of neuromuscular proprioception, pain management, hand manipulation skills and dexterity training were provided to the participants. These interventions are performed in the outpatient occupational therapy center in three sessions per week, for ten weeks and each session is one hour, These interventions are implemented by an occupational therapist who has at least 2 years of practical experience.

#### **Category**

Rehabilitation

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

School of Rehabilitation Sciences of Iran University of Medical Sciences

##### **Full name of responsible person**

Esmail sadeghi

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School of Rehabilitation, Madadkaran Alley, Shahnazari Street, Madar Square, Mirdamad Boulevard

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## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

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##### **Full name of responsible person**

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#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes  
**Title of funding source**  
Iran University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

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## Person responsible for updating data

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

Demographic data of the study participants after making them unidentifiable; Primary and secondary outcome information

### When the data will become available and for how long

After publishing the results of the study

### To whom data/document is available

Researchers who are working in academic and scientific institutions

### Under which criteria data/document could be used

For doing meta-analysis review studies

### From where data/document is obtainable

Esmail sadeghi Phone number:00989120302534 Email

address: sadeghi.ot87@gmail.com Address: School of Rehabilitation, Madadkaran Alley, Shahnazari Street, Madar Square, Mirdamad Boulevard, Tehran, Iran 2) Afsoon Hassani Mehraban Phone number: 0098 21 22228051 Email address: mehraban.a@iums.ac.ir Address: School of Rehabilitation, Madadkaran Alley, Shahnazari Street, Madar Square, Mirdamad Boulevard, Tehran, Iran

**What processes are involved for a request to access data/document**

The researcher can access the data of this research up to one month after sending the request and attaching the registered protocol of the review article to the introduced emails.

**Comments**